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10/586,688	11/06/2006	Makoto Suematsu	K2100.0001	7334
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DICKSTEIN SHAPIRO LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) NEW YORK, NY 10036-2714			NOBLE, MARCIA STEPHENS	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,688	Applicant(s) SUEMATSU ET AL.
	Examiner MARCIA S. NOBLE	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 and 12-21 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-10 and 12-21 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 July 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1668)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status of Claims

Claims 1-10 and 12-21 are pending. Claims 1, 12, and 17 are amended and claims 11, and 22-23 are canceled by the amendment filed 2/23/2009.

Withdrawn Rejections/Objections

The rejection of claims 1-16, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A carrier comprising a non-cationic surface that accumulates on an endothelial cell site of damaged tissue;

A pharmaceutical composition comprising a carrier comprising a non-cationic surface that accumulates on an endothelial cell site of damaged tissue, wherein the carrier also comprises a drug; and

A drug delivery method comprising administering the pharmaceutical composition (disclosed above) to an endothelial cell site of tissue damage in a subject, wherein the composition accumulates at said site and wherein the drug of said composition acts on the site of tissue damage.

The specification does not reasonably provide enablement for 1) a carrier that accumulates on a damaged tissues site that does not expose or comprise endothelial cells; and 2) a method that does not administer the carrier to a site of tissue damage, as set forth in the Office Action, mailed 10/23/2008 (pp.2-5), is withdrawn.

The rejection of claims 15 and 16, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the Office Action, mailed 10/23/2008 (p. 6), is withdrawn.

The objection to claims 11-21, under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form, as set forth in the Office Action, mailed 10/23/2008 (p. 6), is withdrawn.

The rejection of claims 1-12 and 15, under 35 U.S.C. 102(b) as being anticipated by Debs et al (US Patent No. 5,641,662, date of patent: 6/24/1997), as set forth in the Office Action, mailed 10/23/2008 (pp. 7-8), is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following modification to the rejection of record is necessitated by the amendment to the claims:

Claims 17-21, as amended or previously presented, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: A drug delivery method comprising administering the pharmaceutical composition of claim 12 to a damaged endothelial cell site of tissue comprising endothelial cells in a subject, and allowing said composition to accumulate on the damaged endothelial cell site, and; A drug control method comprising administering the pharmaceutical composition of claims 12 to a damaged endothelial cell site of tissue comprising endothelial cells in a subject, allowing said composition to accumulate on the damaged endothelial cell site, and allowing the drug to act on the damaged site.

The specification does not reasonably provide enablement for 1) a method that accumulates on a damaged tissues site that does not expose or comprise endothelial cells; and 2) a method that does not administer the carrier specifically to a site of tissue damage. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the

invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

1) The breadth of the instant claims encompasses a drug delivery method that uses carrier that accumulates on a damaged tissues site that does not expose or comprise endothelial cells. However, the specification discloses, "A tissue for accumulating the carrier of the invention is not particularly limited as long as it comprises endothelial cells." (See p. 15, lines 7-8 of the specification.) The specification also discloses, "The carrier of the invention does not accumulate on an undamaged blood vessel and instead specifically accumulates on an endothelial cell sites damaged as described above." (See p. 15, lines 13-15 of the specification). Therefore, the specification discloses that invention at the very least must comprise the limitation of an endothelial cell site of damage because the carrier only accumulates on endothelial cell sites. Amended claim 17 still recites "accumulate on a damaged site of tissue" and claim 18 still recites "a damaged site of a tissue". These recitations more broadly encompass a site of damage that does not comprise an endothelial cell site. However, the specification guidance provided by the specification suggests that the instant invention would not function with a site of damage that does not comprise endothelial cells because accumulation of the carrier on endothelial cells is the mechanism by which the instant invention functions. Therefore, because the instant carrier specifically functions by accumulation on endothelial cells, as taught by the

specification, the specification does not enable the use of the instant carrier with a site of damage that does not comprise endothelial cells, as is embraced by the claims.

2) The method of claim 18 encompasses a drug delivery method that does not have the active step of administering the carrier comprising a drug to a subject. It is well established in the art for a drug to be delivered to a site of tissue damage it must be administered to a site of tissue damage. The teachings of the specification clearly teach that the instant invention is meant to treat sites of tissue damage and individuals (p. 1, line 12 to p. 2, line 21). However, the claims do not require administering the carrier. Therefore, for the claimed method to be enabled by the specification, the instant claims required an active administration step because the invention would not function without such an administration step.

Overall, the instant claims embrace carriers and methods of using such carrier in a way that is not enabled by the specification. The specification clearly teaches that the carrier functions by accumulation on endothelial cells. However, the breadth of the claims encompasses a site of tissue damage without endothelial cells present. The breadth of the claims also encompasses a drug delivery method that does not administer the drug carrier. From the specification and teachings well established in the art, clearly these embodiments would not function. Therefore, these embodiments are not enabled by the specification. Therefore the instant claims are only enabled for the embodiments disclosed above.

Applicant's arguments filed 2/23/2009 have been fully considered but they are not persuasive. Applicant asserts that the claims have been amended and the amendments overcome the issues of enablement. Applicant's arguments are not found persuasive because the method claims still encompass any site of tissue damage and still lack essential steps, such as the administering step, as discussed above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 and 12-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kazuo et al (JP 07-089874 (publication date: 4/04/1995; abstract is of record in the IDS, filed 7/20/2006; translation p. 1-23 provided by STIC translation), as evidenced by Dictionary.com (<http://dictionary.reference.com/browse/tinge>).

Kazuo et al discloses a drug carrier tinged with positive charges in its surface that recognizes a blood vessel endothelium damage (p. 4, [0013], lines 1 to p. 5, line 2).

According the Dictionary.com., the definition of "tinge" is "a slight admixture, as of some qualifying property or characteristic; trace; smattering" (see page 1 of Dictionary.com printout, definition # 4). Therefore, Kazuo et al discloses a drug carrier with only trace amount of positive charge on its surface which would not affect the overall neutral or anion charge. Therefore, Kazuo et al inherently discloses a non-cationic surface drug carrier as claimed, as evidenced by Dictionary.com. Furthermore, Kazuo et al discloses that the carrier can be made with such phospholipids as phosphatidylcholine, phosphatidylglycerol, and phosphatidylethanolamine (p. 6, [0036], line 1 to p. 7, line 3). These are the same material disclosed by specification for the production of the claimed carrier (See page 9, lines 5-22). Because Kazuo et al and the specification disclose carrier that are made of the same structural components, inherently the carriers of the instant claims and the carrier disclosed by Kazuo et al are the same. Also because the instantly claimed carrier and the carrier disclosed by Kazuo et al are the same, the carrier disclosed by Kazuo et al inherently has all the same functional properties and can be used for all the disclosed used in claims 1-10.

The amendment to the claim 1 specifies, "wherein the carrier comprises a carboxylic type lipid that has no phosphate group". Given its broadest reasonable interpretation, "a carboxylic type lipid" encompasses any fatty acid, fatty acid-derived or a fatty acid derived amide that does not have a phosphate group. Kazuo et al discloses constructing a liposome comprising 6-o-palmitoyl-methyl-D-galatosaminide, which is a carboxylic lipid that has no phosphate groups (p. 9, [0060], lines 1-3). Therefore, Kazuo et al also teaches the structural limitations added by amendment. The amendment to

claim 1 also specifies that the carrier can accumulate on a damaged endothelial cell site of a tissue comprising endothelial cells. This newly added limitation does not add any structural limitations, inherently the carrier disclosed by Kazuo should accumulate on a damaged endothelial cell site of a tissue comprising endothelial cells because structural it is the same as the claimed carrier.

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972)." "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See also MPEP 2113.

In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ

563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Katzuo et al disclose the drug carrier can be used anti-inflammatory agents, anticancer agents, angiotensin conversion enzyme inhibitor, agents that inhibit smooth muscle cell mobilization, platelet aggregating repressors, and overall inhibitors of thrombolysis (p. 5, [0025], lines 1-6). Therefore, Katzuo et al discloses the limitations of drug transporter and pharmaceutical composition of claims 11-16.

Katzuo et al discloses that the liposome of their invention is administered intravenously to rats comprising blood vessel damage and liposome accumulation was monitored (p. 13, [0091], line 1 to [0092], line 6). Katzuo et al discloses that the liposome accumulated in the endothelial site of blood vessel damage (p. 13, [0096], line 4 to p. 14, line 1). Katzuo discloses the use of the liposome to deliver drugs that depress blood vessel thickening in a site of endothelial cell damage (p. 15, [0113], lines 1-4). Katzuo discloses that the liposome successfully delivered said drugs and blood vessel thickening was suppressed at the site of damage (p. 16, [0116], lines 1-2). Therefore, Katzuo et al discloses a method comprising accumulation of the carrier at a damage site in a blood vessel and allowing the drug to act on the damaged site, as claimed in claims 17-21.

Overall, the prior art of Katzuo et al explicitly or inherently discloses all the properties of the claimed invention. Therefore, Katzuo et al anticipates the instant claims.

Applicant's arguments filed 2/23/2009 have been fully considered but they are not persuasive. Applicant asserts that the amendment to the claims overcome the instant rejection because Kazuo does not disclose that the carrier comprises a carboxylic type lipid that has no phosphate groups. Applicant's argument is not found persuasive because Kazuo discloses a liposome comprising 6-o-palmitoyl-methyl-D-galatosaminide, which is a carboxylic lipid that has no phosphate groups. Therefore, contrary to Applicant's arguments, Kazuo does disclosed the claimed invention.

The following rejection is necessitated by the amendments to the claims:

Claims 1-10 and 12-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsuchida (US 6,949,663 B2 date:9/27/2005; effective filing date:11/9/2001).

The applied reference has a common inventor (Shinji Takeoka) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Amended claim 1 encompasses a carrier comprising the structural elements of a carboxylic type lipid that has no phosphate group. Tsuchida discloses these structural limitations (col 1, lines 58-59). The preamble of the claim also indicates that carrier has

a non-cationic surface. Tsuchida discloses that the carboxylic lipid is stably fixed to phospholipid bilayer membranes (col 1, lines 60-63). Claim 1 also recites, "which can accumulate on a damaged endothelial cell site of a tissue comprising endothelial cells". These limitations to not add additional structural limitations to the claims carrier. Therefore, these disclosures by Tsuchida encompass the limitations of claims 1 and 2 and inherently, the disclosed carrier should "accumulate on a damaged endothelial cell site of a tissue comprising endothelial cells" because the structure of Tsuchida is the same as claimed carrier.

Claims 3-10 also do not provide any additionally structural limitations. Therefore, the disclosure by Tsuchida encompasses the limitations of claims 3-10.

Claim 12 encompasses pharmaceutical composition of claim 1 incorporating or carrying a drug. Given its broadest reasonable interpretation, "incorporating or carrying a drug" encompasses the presence of any substance in the carrier carried by or that is part of the carrier that is deliverable to a subject. Therefore, the carrier itself can be considered a drug and encompasses the limitations of the claims. Tsuchida discloses that the carboxylic lipids incorporated into membrane vesicles are administered to the body and used in pharmaceutical compositions (col 1, lines 20-24, col 2, lines 60-65, and col 13, lines 64-67). Claim 13 recites that the carrier functions as a drug for controlling a platelet function. Tsuchida discloses that the carboxylic lipid composition prevents aggregation of platelets (col 1, lines 60-67), therefore disclosing a drug for controlling a platelet function. Claim 14 specifies that the drug is a substance that is activated by inflammatory cells and is an antithrombotic agent. Tsuchida discloses that

the liposome components cause thrombocytopenia and dysfunction of white blood cells (col 1, lines 36-39) and the carboxylic lipid counter these side effects (col 1, lines 48-53). Therefore, Tsuchida discloses the limitations of claims 14-16.

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product (*In re Ludtke*). Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972)." "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See also MPEP 2113.

In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Overall, the prior art of Tsuchida explicitly or inherently discloses all the properties of the claimed invention. Therefore, Tsuchida anticipates the instant claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is necessitated by the amendment to the claims:

Claims 1-10 and 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites, "a carboxylic type lipid". This recitation is indefinite because the specification does not define this term and it is not apparent how similar or different "a carboxylic type lipid" is to a carboxylic lipid. Claims 2-10 and 12-21 depend upon claim 1.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following rejection is necessitated by the amendments to the claims:

Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,949,663.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application encompass the same limitations of the patent claims.

Claims 1-10 have the structural limitations of being non-cationic and being carboxylic type lipids having no phosphate groups. Claims 1-8 are all non-cationic and are carboxylic type lipids having no phosphate groups. Therefore, it would be obvious to an artisan that the claims of the patent and the copending application are not patentably distinct.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

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